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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,326	09/10/2003	Andreas Steinmeyer	SCH-1585D3	1878

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EXAMINER

QAZI, SABIHA NAJM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/658,326	Applicant(s) STEINMEYER ET AL.	
	Examiner Sabiha Qazi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/10/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 11-34 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 11-26,33 and 34 is/are allowed.
- 6) ☐ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 11-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/180,018.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 11-34 are pending. Amendments are entered.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 11-26, 33 and 34 drawn to vitamin D compounds, compositions and their process of making, classified in class 552, subclass 653; class 514 and subclass 167.

II. Claims 27-32 are drawn to method of use of the compounds of formula I as in claim 11, classified in class 514, subclass 167.

The inventions are distinct, each from the other because of the following reasons:

Inventions of group and I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product.

1. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Attorney Brion Heaney on 10/5/2005, a provisional election was made with traverse to prosecute the invention of group I, claims 11-26, 33 and 34. Applicant in replying to this Office action must make affirmation of this election. Claims 27-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Rejoinder of Method claims

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6. When the invention of group I would be allowed the methods of group II would be rejoined with the compounds of invention of group I.

Non-Final Office Action

Claims 11-26, 33 and 34 are allowed. Claims 27-32 are drawn to method of use. These claims will be rejoined because compounds are allowable.

Allowable Subject Matter

7. Claims 11-26, 33 and 34 are allowed. Closest prior art is WO 97/41096. Prior art does not teach nor suggest the substitution of phenyl group at C-25 (Z).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-32 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain diseases, does not reasonably provide enablement for the treatment of all the disease as claimed. Claims are drawn to the treatment of AIDS, Alzheimer's and various other diseases by vitamin D compounds. Since these diseases are not treated by vitamin D compounds

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Claims are rejected because there is a lack of enablement for the method for treatment of the diseases listed in the claims.

The nature of the invention

Presently claimed invention is drawn to a method for treatment of various diseases as in claims 27-32

Hyperproliferation and deficient cell differentiation

- Disequilibrium of the immune system
- Steroid induced osteoporosis
- Senile osteoporosis
- Degenerative diseases of the peripheral and central nervous system
- Melanomas
- Betazell carcinoma
- Squamous carcinoma
- Actinic keratoses
- Cervix dysplasias
- Tumors of intestine
- Carcinoma of breast
- Acne
- Lung tumors
- Prostate carcinomas

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- Leukemias
- Ichthyosis
- Pruritus
- Inflammatory disease
- Eczema
- Disease of the Atropic Formon series
- Rheumatoid arthritis
- Asthma
- Respiratory tract disease
- An autoimmune disease
- Multiple sclerosis
- Diabetes mellitus type I
- AIDS
- Rejection in case of autologous, allogeneic or Xenogeneic transplants

and many more.

The predictability or unpredictability of the art:

There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Therefore predicting the method of treating or inhibiting various disease states by compounds of broad genus of vitamin D is impossible. For example MIYAMOTO et al. (US Patent 6,124,276) discloses vitamin D compounds useful the treatment of osteoporosis, and as antitumor agent. Steinmeyer et al. (WO 97/41096 and WO 94/00428) discloses vitamin D compounds useful for the treatment of osteoporosis and hyperproliferative skin diseases. DeLuca et al. (US Patent 6,127,559) discloses the use of vitamin D compounds for treatment of psoriasis, osteoporosis and for certain cancers. Reddy (US Patent 6,479,538) discloses various vitamin D compounds useful for inhibiting the proliferation and/or inducing the differentiation of a hyperproliferative skin cell. DeLuca et al.

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(US Patent 5,945,410) discloses the method of treatment for metabolic bone disorder. However, none of them teaches the treatment of AIDS or Alzheimer's disease by vitamin D compounds.

IT is therefore impossible to predict the treatment of certain diseases such as AIDS or Alzheimer's diseases in this case.

The amount of direction or guidance presented

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat* et al. (CCPA 1964) 327 F.2d 685, 140 USPQ 471; *In re Barr* et al. (CCPA 1971) 444 F.2d 349, 151 USPQ 724.

In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result".

See *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity).

See also *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), this is because it is not obvious from the disclosure of one species, what other species will work.

The presence or absence of working examples

There no examples or test data in vivo or in vitro to support all the methods of treatment as presently claimed. In the disclosure on page 25 Applicant disclose that the compounds of the invention are suitable for the treatment of listed diseases.

On page 26, the increase in thickness of the epidermis is described on skin of mice. On page 28 it states, "In addition, it has been found that certain compounds of general formula I in HL 60 cells

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The quantity of experimentation necessary

Since different aspects of biological activity cannot be predicted but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue experimentation study.

Since the nature of the method is so unpredictable, and since the claims are drawn to a broad range of pharmaceuticals for treatment of such a broad range of diseases such as AIDS, Alzheimer's and since there is a lack of guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan, Sreeni (acting) can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thursday, December 08, 2005



SABIHA QAZI, PH.D
PRIMARY EXAMINER